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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,366	12/03/2003	Claudio Soto-Jara	009621-34567 DIV	8149

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,366	SOTO-JARA, CLAUDIO	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-14 and 18-28* is/are pending in the application.

4a) Of the above claim(s) *1-11,13,14,19-21,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,18,22-24* is/are rejected.

7)☐ Claim(s) *27 and 28* is/are objected to.

8)☒ Claim(s) *1-14, 18-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 10 March 2006 has been entered in full. Claims 12, 18, and 22 are amended. Claims 27-28 are added. Claims 15-17 are cancelled.

Claims 1-11, 13-14, 19-21, and 25-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 August 2005.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12, 18, 22-24, 27, and 28 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the specification at pg 3 of the previous Office Action (21 November 2005) is *withdrawn* in view of the amended abstract (10 March 2006).

2. The objection to claim 17 at pg 3 of the previous Office Action (21 November 2005) is *withdrawn* in view of the cancelled claim (10 March 2006).

3. The rejection of claims 12, 15-18, and 22-24 under 35 U.S.C. § 112, first paragraph (written description) as set forth at pg 3-6 of the previous Office Action (21 November 2005) is *withdrawn* in view of the amended claims (10 March 2006).

4. The rejections of claims 12 and 15-18 under 35 U.S.C. § 112, second paragraph as set forth at pg 6-7 of the previous Office Action (21 November 2005) are *withdrawn* in view of the amended and cancelled claims (10 March 2006).

5. The rejection of claim 22 on the ground of nonstatutatory obviousness-type double patenting as set forth at pg 7-8 of the previous Office Action (21 November 2005) is withdrawn in view of the amended claim (10 March 2006). Please see new Double Patenting rejection, below.

6. The rejection of claims 12, 17-18, and 22-24 under 35 U.S.C. § 102(b) as set forth at pg 8-9 of the previous Office Action (21 November 2005) are withdrawn in view of the amended and cancelled claims (10 March 2006).

7. The rejection of claims 15-16 under 35 U.S.C. § 103(a) as set forth at pg 9-11 of the previous Office Action (21 November 2005) is withdrawn in view of the cancelled claims (10 March 2006).

8. The supplemental information disclosure statement filed on 10 March 2006 has been considered.

Claim Objections

9. Claims 12, 22, 27, and 28 are objected to because of the following informalities:

9a. Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9b. In claims 12 and 22 (line 10), the phrase "an altered" should be amended to recite "an alteration of the" or "altering a".

Appropriate correction is required.

Double Patenting

10. Claims 12, 18, and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6, 8, 10, 11, and 13 of U.S. Patent No. 5,948,763 in view of Findeis et al. (WO 96/28471). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for reducing the formation or amount of amyloid or amyloid-like deposits involving the abnormal folding of amyloid into a β-sheet structure comprising contacting the amyloid protein prior to or after the abnormal folding thereof into a β sheet structure with a peptide. The patented claims which recite methods of reducing the formation or amount of amyloid or amyloid-like deposits comprising contacting the amyloid protein with an inhibiting peptide comprising a portion of three to eight amino acids, which portion is hydrophobic and has one or more proline residues therein, said inhibitory peptide having a length of three to fifteen amino acids render obvious the pending claims of methods of reducing the formation or amount of amyloid or amyloid-like deposits comprising contacting the amyloid protein with a peptide consisting of SEQ ID NO: 1 (Leu-Pro-Phe-Phe-Asp) which is chemically modified. The patented claims also recite that at least some of the amino acid residues are D-amino acid residues. The patented claims also recite that the inhibitory peptide has the sequence of SEQ ID NO: 18 (Leu-Pro-Phe-Phe-Asp), which is SEQ ID NO: 1 of the instant application.

Although the '763 patent does not teach that the inhibiting peptide is chemically modified, Findeis et al. teach a peptide that binds to natural β amyloid peptides, modulates the aggregation of natural β amyloid peptides, and that the peptide may be modified at the amino terminus, carboxy terminus, or both, with such groups as amide groups, alkyl or aryl amide

groups, and hydroxyl groups (pg 3-6, 11, 14, last paragraph through pg 15). Findeis et al. disclose that modifying groups can be attached to the peptidic component by standard methods, for example using methods for reaction through an amino group, a carboxyl group, a hydroxyl group, or other suitable reactive group on an amino acid side chain (pg 25, lines 37-38 through pg 26, lines 1-2; pg 30, lines 27-39). Furthermore, Findeis et al. teach a method for inhibiting the formation of natural β-amyloid peptide deposits comprising contacting the natural β-amyloid peptides with a modified modulator peptide such that aggregation of the natural β-amyloid peptides is inhibited (pg 6, lines 24-30; pg 37; pg 39, lines 8-36). Findeis et al. state that the method may be used to treat clinical occurrences of β amyloid deposition, such as Alzheimer's disease and Down's syndrome (pg 40, lines 11-20).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method for reducing the formation of amyloid deposits comprising contacting the amyloid protein with an inhibitory peptide of SEQ ID NO: 18 as taught by the '763 patent by chemically modifying the peptide as taught by Findeis et al. The person of ordinary skill in the art would have been motivated to make that modification because amyloid beta protein plays role in the pathogenesis of Alzheimer's disease and chemically modified peptides have increased stability, bioavailability, and solubility (Findeis et al. pg 13, lines 13-15). The person of ordinary skill in the art reasonably would have expected success because similar chemical modifications of peptides to increase stability, bioavailability, and permeability were already being performed at the time the invention was made. Therefore, the instant claims reciting a method for reducing the formation of amyloid or amyloid-like deposits involving abnormal folding into β sheet structuring comprising bringing into the presence of said

amyloid β peptide an effective amount of a peptide analog generated by chemical modification of the peptide consisting of SEQ ID NO: 1 (Leu-Pro-Phe-Phe-Asp) is not patentably distinct over the issued claims in U.S. Patent No. 5,948,763 in view of Findeis et al.

Claim Rejections - 35 USC § 103

11. Claims 12, 18, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findeis et al. (WO 96/28471) in view of Soto et al. (Nat Med 4(7): 822-826, July 1998).

Findeis et al. teach a peptide that binds to natural β amyloid peptides and modulates the aggregation of natural β amyloid peptides (pg 3-6, 11). Findeis et al. also teach that the peptide may be modified at the amino terminus, carboxy terminus, or both, with such groups as amide groups, alkyl or aryl amide groups, and hydroxyl groups (pg 14, last paragraph through pg 15). Findeis et al. disclose that modifying groups can be attached to the peptidic component by standard methods, for example using methods for reaction through an amino group, a carboxyl group, a hydroxyl group, or other suitable reactive group on an amino acid side chain (pg 25, lines 37-38 through pg 26, lines 1-2; pg 30, lines 27-39). Furthermore, Findeis et al. teach a method for inhibiting the formation of natural β-amyloid peptide deposits comprising contacting the natural β-amyloid peptides with a modified modulator peptide such that aggregation of the natural β-amyloid peptides is inhibited (pg 6, lines 24-30; pg 37; pg 39, lines 8-36). Findeis et al. state that the method may be used to treat clinical occurrences of β amyloid deposition, such as Alzheimer's disease and Down's syndrome (pg 40, lines 11-20).

Findeis et al. does not teach a β-sheet breaker peptide comprising iAβ5 (SEQ ID NO: 1).

Soto et al. disclose the β-sheet breaker peptide of iAβ5 of SEQ ID NO: 1 of the instant application. Soto et al. teach *in vitro* and *in vivo* methods for reducing the formation of amyloid

deposits or for reducing the amount of said amyloid β peptide which has already formed into a beta sheet structure comprising contacting the amyloid β peptide prior to or after the abnormal folding thereof into a β sheet structure with an effective amount of iAβ5 peptide (LPFFD; pg 822, 3rd full paragraph; pg 823, col 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method for reducing the formation of amyloid deposits comprising contacting the amyloid protein with chemically modified peptides as taught by Findeis et al. by utilizing the iAβ5 peptide as taught by Soto et al. The person of ordinary skill in the art would have been motivated to make that modification because amyloid beta protein plays role in the pathogenesis of Alzheimer's disease and chemically modified peptides have increased stability, bioavailability, and solubility (Findeis et al. pg 13, lines 13-15; Soto et al. pg 823, col 2). The person of ordinary skill in the art reasonably would have expected success because non-chemically modified iAβ5 reduced amyloid beta deposition *in vivo* (Soto et al.; pg 823, col 1) and similar chemical modifications of peptides to increase stability, bioavailability, and permeability were already being performed at the time the invention was made (for example, Soto et al., pg 823, col 2). Therefore, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
22 May 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER